DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 19, 2008 has been entered.

Action Summary

The rejection of claims 1, 2, 22, 23 and 26-35 under 35 U.S.C. **112, first** paragraph (enablement) is hereby expressly **withdrawn** in view of Applicants' amendment.

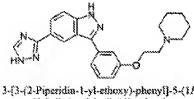
The rejection of claim 31 under 35 U.S.C. **112, second** paragraph, as being indefinite is being **maintained** for the reasons stated in the previous Office Action.

The rejection of claims 1, 28-35 under 35 U.S.C. **102(e)** as being anticipated by Bhagwat et al. (U.S.Patent No. 6,897,231 B2) is being **maintained** for the reasons stated in the previous Office Action.

The rejection of claims 1, 28-31 under 35 U.S.C. **102(e)** as being anticipated by Bhagwat et al. (U.S.Patent No. 6,897,231 B2) evidenced by Sanders et al. (U.S. patent No. 5,766,605 A) or Mathias (U.S. patent No. 5,4341,36A) is being **maintained** for the reasons stated in the previous Office Action.

The rejection of claims 1, 28-31 under 35 U.S.C. **102(e)** as being anticipated by Stein et al. (US 2004/0067953A1) is being **maintained** for the reasons stated in the previous Office Action.

Applicant's are reminded of Applicants' election **without traverse** of Group I, claims 1, 2, 5-11, 22, 23 and 26-35 drawn to a method for treating, preventing managing and/or modifying pain in a patient, comprising administering to a patient in need there of an effective amount of a compound having the formula set forth in claims 2, 5-11 and 23 with an election of species of 3-(3-(2-(piperidin-1-yl)ethoxy)phenyl)-5-(1H-1,2,4-triazol-3-yl)-1H-1H-indazole having the following structure:



3-[3-(2-Piperidin-1-yl-ethoxy)-phenyl]-5-(1*H*-[1,2,4]triazol-3-yl)-1*H*-indazole ;

Claims 1, 2, 22, 23 and 26-35 have been examined only to the extent of applicants' elected species of 3-(3-(2-(piperidin-1-yl)ethoxy)phenyl)-5-(1H-1,2,4-triazol-3-yl)-1H-1H-indazole.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation of "**..pain is… lost hair, dry hand, color change to the skin, weakness, edema, increased sweating..etc**" renders the claim vague and indefinite because above conditions that equates the term "pain" where applicants act as his or her own lexicographer to specifically define a term of a claim **contrary to its ordinary meaning**, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "**"pain**" in claim 31 is used by the claim to mean "**lost hair, dry hand, color change to the skin, weakness, edema, increased sweating..etc**", while the accepted meaning is "pain, hyperalgesia, nociception etc.." The term is indefinite because the specification does not clearly redefine the term.

The phrase "**another** painful neuropathic condition" renders the claim vague because it is not clear that **"another"** painful neuropathic condition is intended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2 and 28-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Bhagwat et al. (U.S.Patent No. 6,897,231 B2).

Bhagwat et al. teach that Applicants' active agent is useful for the treatment of stroke, asthma, osteoarthritis, rheumatoid arthritis, gout, burn from exposure to fire, chemical radiation, traumatic injury and lupus erythematosus, diabetes and cancers of a variety of tissues.

Accordingly, the claims are clearly anticipated by the cited reference because the subject population "a patient in need thereof" to be treated are the same. Bhagwat et al. teach that Applicants' active agent is useful for treatment of osteoarthritis, rheumatoid arthritis, gout, burn from exposure to fire, chemicals radiation, traumatic injury and cancer exhibit/develop pain. Therefore, patients disclosed by Bhagwat et al. are "in need of" treating pain as instantly claimed. In this case the Bhagwat et al. methodology meets all elemental steps of the instant claims, accordingly, Bhagwat et al. inherently achieve all functional clinical effects subsequent to the administration of the same active agent to the same subject population (in need thereof). Since Bhagwat et

al's method steps are the same Bhagwat et al.'s method inherently achieve the same clinical results instantly claimed.

Claims 1, 2 and 28-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Bhagwat et al. (U.S.Patent No. 6,897,231 B2) evidenced by Sanders et al. (U.S. patent No. 5,766,605 A) or Mathias (U.S. patent No. 5,4341,36A).

Bhagwat et al. teach that Applicants active agent is useful for the treatment and prevention of lupus erythematosus and asthma.

Applicants claiming the treatment of pain equates to a "complex regional pain syndrome" as an **autonomic dysfunction**.

Sanders et al. teach that asthma is autonomic dysfunction. (abstract, claim 1)

Mathias teaches that Lupus Erythematosus is an autonomic dysfunction. (column 1, lines 11-20).

Accordingly, the claims are clearly anticipated by the cited reference because the subject population "a patient in need thereof" to be treated are the same. Bhagwat et al. teach that Applicants' active agent is useful for treatment of lupus erythematosus and asthma equate to pain set forth in claim 31. Therefore, patients disclosed by Bhagwat et al. are "in need of" treating pain as instantly claimed. In this case the Bhagwat et al. methodology meets all elemental steps of the instant claims, accordingly, Bhagwat et al. inherently achieve all functional clinical effects subsequent to the administration of the same active agent to the same subject population (in need thereof). Since Bhagwat et

al's method steps are the same Bhagwat et al.'s method inherently achieve the same clinical results instantly claimed.

Therefore, Bhagwat et al. clearly anticipates Applicants' claiming invention.

Claims 1, 2 and 28-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Stein et al. (US 2004/0067953A1).

Stein et al. teach the treatment of cancer by the administration of an effective amount of Applicant's active agent. (abstract, Figure 6, C).

Accordingly, the claims are clearly anticipated by the cited reference because the subject population "a patient in need thereof" to be treated are the same. Stein et al. teach the treatment of cancer by the administration of an effective amount of Applicant's active agent. Therefore, patients disclosed by Stein et al. are "in need of" treating pain as instantly claimed because it is well known in the art that pain is associated with cancer. In this case the Stein et al. methodology meets all elemental steps of the instant claims, accordingly, Stein et al. inherently achieve all functional clinical effects subsequent to the administration of the same active agent to the same subject population (in **need** of treating pain). Since Stein et al's method steps are the same Bhagwat et al.'s method inherently achieves the same clinical results instantly claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22, 23, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhagwat et al. (U.S.Patent No. 6,897,231 B2).

Bhagwat et al's teaching as applied as before. Bhagwat et al. teach that compounds can be administered together with another biologically active agent. (particularly column 24, line 40). Bhagwat et al. teach that the compound can be formulated with a local anesthetic such as Lignocaine to ease pain at the site of the injection. (column 26, lines 25-30).

Bhagwat et al. do not teach the specific agents set froth in claim 27.

It would have been obvious to one of ordinary skill in the art to combine an anesthetic including ketamine with Bhagwat et al's compound because Bhagwat et al.

teach that any biologically active agent can be combined with Bhagwat et al's compound and because a local anesthetics can ease pain at the site of the injection. One would have been motivated to combine any anesthetic such as ketamine together with Bhagwat et al's compound in order to avoid pain at the injection site by combining an local anesthetic including ketamine.

None of the claims are allowed.

Response to Arguments

Applicants' arguments filed March 19, 2008 have been fully considered but they are not persuasive. With regard to 35 U.S.C.112, second paragraph rejection, Applicants argue that claim 31 has been amended to recite that the pain can be "associated with" recited conditions to overcome the rejection. This is not found persuasive because the claim as amended still equates the term "pain" that is contrary to its ordinary meaning. (see the rejection). Therefore, the term is indefinite because the specification does not clearly redefine the term as such.

With respect to 35 U.S.C. 102(e) rejection over U.S.Patent No. 6,897,231 B2 (Bhagwat et al.), Applicants essentially argue that the literature references and examples discussed to demonstrate that pain and any underlying condition are separate

entities with respect to their treatment and that pain itself should be considered as a disease in its own right. Applicants also argue that the claims 1 and 2 have been amended to recite method for treatment. This is not persuasive because Applicants literature references and examples submitted to demonstrate that pain and any underlying condition are separate entities, they contradict with what is instantly claimed, for examples claim 31 equates all of the underlying disease equate to pain. Further, the claims as amended are anticipated by the cited reference because the subject population "a patient in need thereof" to be treated are the same. Bhagwat et al. teach that Applicants' active agent is treatment of osteoarthritis, rheumatoid arthritis, gout, burn from exposure to fire, chemicals radiation, traumatic injury and cancer exhibit/develop pain. Therefore, patients disclosed by Bhagwat et al. encompass the same subject population "in need of" treating pain as instantly claimed.

With respect to 35 U.S.C. 102(e) rejection over U.S.Patent No. 6,897,231 B2 (Bhagwat et al.), evidenced by U.S.Patent No. 5,766,605 or U.S.Patent No. 5,434,136; and 35 U.S.C. 102(e) rejection over (U.S.2004/0067953A1), Applicants essentially argue that the claims 1 and 2 have been amended to recite method of treatment to overcome rejections. This is not found to be persuasive because the claim as amended still equates the term "pain" with those underlying disease such as cancer, asthma and lupus erythematosus. (see claim 31). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
June 3, 2008